IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA CHARLESTON DIVISION

In Re: Coloplast Corp. Pelvic Support Systems

**Products Liability Litigation** 

**MDL 2387** 

DEFENDANT MENTOR WORLDWIDE LLC'S ANSWER AND AFFIRMATIVE DEFENSES TO FIRST AMENDED MASTER LONG FORM COMPLAINT

Defendant Mentor Worldwide LLC ("Mentor") responds to Plaintiffs' First Amended Master Long Form Complaint and Jury Demand (the "Complaint") as follows:

# I. RESPONSE TO PARTIES

# A. Response to "Plaintiffs"

- 1. Mentor lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in Paragraph 1 of the Complaint, and on that basis, denies them.
- 2. Mentor lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in Paragraph 2 of the Complaint, and on that basis, denies them.

# B. Response to "Defendants"

3. Mentor lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in Paragraph 3 of the Complaint, and on that basis, denies them.

- 4. In response to Paragraph 4 of the Complaint, Mentor admits that it is a limited liability company organized and existing under the laws of the State of Delaware. Mentor further admits that the address of its registered agent in Delaware is 1209 Orange Street, Wilmington, Delaware 19801, and that its principal place of business is located at 5425 Hollister Avenue, Santa Barbara, CA 93111. Mentor also admits that its sole member is Ethicon, Inc., that Ethicon, Inc.'s principal place of business is located in Somerville, New Jersey, and that Ethicon, Inc. is a wholly owned subsidiary of Johnson & Johnson. The remaining allegations contained in Paragraph 4 are legal conclusions that do not require an answer.
- 5. Mentor lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in Paragraph 5 of the Complaint, and on that basis, denies them.
- 6. Mentor lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in Paragraph 6 of the Complaint, and on that basis, denies them.
- 7. Mentor lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in Paragraph 7 of the Complaint, and on that basis, denies them.
- 8. Mentor lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in Paragraph 8 of the Complaint, and on that basis, denies them.
- 9. Paragraph 9 of the Complaint contains no factual allegations and thus no response is required.

- 10. Paragraph 10 of the Complaint contains no factual allegations and thus no response is required.
- 11. Paragraph 11 of the Complaint contains no factual allegations and thus no response is required.
- 12. Paragraph 12 of the Complaint contains no factual allegations and thus no response is required.
- 13. Paragraph 13 of the Complaint contains no factual allegations and thus no response is required.
- 14. Paragraph 14 of the Complaint contains no factual allegations and thus no response is required.
- 15. Paragraph 15 of the Complaint contains no factual allegations and thus no response is required.
- 16. Mentor lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in Paragraph 16 of the Complaint, and on that basis, denies them.
- 17. In response to Paragraph 17 of the Complaint, Mentor incorporates by reference the admissions, denials, and averments of any Master Long Form Answer it has filed or will file in its and other Defendants' MDLs.
  - 18. Mentor denies the allegations contained in Paragraph 18 of the Complaint.

# II. RESPONSE TO JURISDICTION AND VENUE

19. In response to Paragraph 19 of the Complaint, Mentor admits that in each of the constituent actions, Plaintiffs are purporting to seek damages in excess of \$75,000 and that

subject matter jurisdiction is proper pursuant to 28 U.S.C. § 1332. The remaining allegations contained in Paragraph 19 are legal conclusions that do not require an answer.

- 20. The allegations contained in Paragraph 20 are legal conclusions that do not require an answer.
- 21. Mentor is without information or knowledge sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 21, and on that basis, denies them.

# III. RESPONSE TO DEFENDANTS' PELVIC MESH PRODUCTS

- 22. In response to Paragraph 22 of the Complaint, Mentor admits that it distributed certain products through June 2, 2006, indicated for the treatment of stress urinary incontinence or pelvic organ prolapse and that certain of such products were cleared for sale by the FDA through the 510(k) process, but denies the remaining allegations contained in Paragraph 22 regarding the 510(k) process. Mentor is without information or knowledge sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 22, and on that basis, denies them.
- 23. In response to Paragraph 23 of the Complaint, Mentor admits only that it distributed Aris Transobturator Tape, Suspend-Tutoplast Processed Fascia Lata and Axis-Tutoplast Processed Dermis through June 2, 2006. Mentor is without information or knowledge sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 23, and on that basis, denies them.
  - 24. No response is required to Paragraph 24.

# IV. RESPONSE TO FACTUAL BACKGROUND

- 25. In response to Paragraph 25 of the Complaint, Mentor admits only that it distributed Aris Transobturator Tape, Suspend-Tutoplast Processed Fascia Lata and Axis-Tutoplast Processed Dermis through June 2, 2006. Mentor is without information or knowledge sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 25, and on that basis, denies them.
- 26. In response to Paragraph 26 of the Complaint, Mentor admits that transvaginal mesh is one treatment for pelvic organ prolapse and stress urinary incontinence. Mentor denies, generally and specifically, each and every remaining allegation of Paragraph 26.
- 27. Mentor admits the general factual statements contained in Paragraph 27 of the Complaint.
- 28. Mentor admits the general factual statements contained in Paragraph 28 of the Complaint.
- 29. Mentor is without information or knowledge sufficient to form a belief as to the truth of the allegations contained in Paragraph 29 of the Complaint, and on that basis, denies them.
- 30. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 30 of the Complaint.
- 31. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 31 of the Complaint.
- 32. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 32 of the Complaint.

- 33. Mentor is without information or knowledge sufficient to form a belief as to the truth of the allegations contained in Paragraph 33 of the Complaint, and on that basis, denies them.
- 34. In response to Paragraph 34 of the Complaint, Mentor admits that on February 9, 2001, it announced the completion of the acquisition of Porges S.A., a subsidiary of Sanofi-Synthelabo and Synthelabo Biomedical. Mentor further admits that at the time of the acquisition, Porges S.A. manufactured a range of urological products including transvaginal mesh, held the leading market share for urological products in France, and had a strong position throughout Europe. Mentor is without information or knowledge sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 34, and on that basis, denies them.
- 35. In response to Paragraph 35 of the Complaint, Mentor states that the quoted press releases speak for themselves, and Mentor refers to the complete press releases for a full statement of their contents. Mentor is without information or knowledge sufficient to form a belief as to the truth of the allegations relating to ABISS, and on that basis, denies them. Mentor denies, generally and specifically, each and every remaining allegation of Paragraph 35.
- 36. In response to Paragraph 36 of the Complaint, Mentor admits that it entered into a number of agreements in 2005 pursuant to which ABISS licensed certain products to be distributed by Mentor. Mentor admits that it sold its urology business, including the Aris Transobturator Tape, Suspend-Tutoplast Processed Fascia Lata and Axis-Tutoplast Processed Dermis product lines, to Coloplast on June 2, 2006. Mentor denies, generally and specifically, each and every remaining allegation of Paragraph 36.
- 37. In response to Paragraph 37 of the Complaint, Mentor admits that while it distributed Aris Transobturator Tape through June 2, 2006, Aris Transobturator Tape was

manufactured by ABISS. Mentor is without information or knowledge sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 37, and on that basis, denies them.

- 38. Mentor is without information or knowledge sufficient to form a belief as to the truth of the allegations contained in Paragraph 38 of the Complaint, and on that basis, denies them.
- 39. In response to Paragraph 39 of the Complaint, Mentor admits that on December 27, 2005, it obtained 510(k) clearance for Novasilk Mesh. Further answering, Mentor states that the quoted press release speaks for itself, and Mentor refers to the complete press release for a full statement of its contents. Mentor admits the remaining general factual statements of Paragraph 39.
- 40. Mentor is without information or knowledge sufficient to form a belief as to the truth of the allegations contained in Paragraph 40 of the Complaint, and on that basis, denies them.
- 41. Mentor is without information or knowledge sufficient to form a belief as to the truth of the allegations contained in Paragraph 41 of the Complaint, and on that basis, denies them.
- 42. Mentor is without information or knowledge sufficient to form a belief as to the truth of the allegations contained in Paragraph 42 of the Complaint, and on that basis, denies them.

- 43. Mentor is without information or knowledge sufficient to form a belief as to the truth of the allegations contained in Paragraph 43 of the Complaint, and on that basis, denies them.
- 44. Mentor is without information or knowledge sufficient to form a belief as to the truth of the allegations contained in Paragraph 44 of the Complaint, and on that basis, denies them.
- 45. Mentor states that the quoted FDA Safety Communication referenced in Paragraph 45 speaks for itself and Mentor refers to the complete FDA Safety Communication for a full statement of its contents. Mentor is without information or knowledge sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 45 of the Complaint, and on that basis, denies them.
- 46. Mentor states that the quoted FDA Safety Communication referenced in Paragraph 46 speaks for itself and Mentor refers to the complete FDA Safety Communication for a full statement of its contents.
- 47. Mentor states that the quoted FDA Safety Communication referenced in Paragraph 47 speaks for itself and Mentor refers to the complete FDA Safety Communication for a full statement of its contents. Mentor denies, generally and specifically, the remaining allegations contained in Paragraph 47 of the Complaint.
- 48. Mentor states that the quoted publication, "Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse," referenced in Paragraph 48 speaks for itself and Mentor refers to the complete publication for a full statement of its contents.

- 49. Mentor states that the quoted publication, "Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse," referenced in Paragraph 49 speaks for itself and Mentor refers to the complete publication for a full statement of its contents.
- 50. Mentor states that the quoted publication, "Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse," referenced in Paragraph 50 speaks for itself and Mentor refers to the complete publication for a full statement of its contents.
- 51. Mentor is without information or knowledge sufficient to form a belief as to the truth of the allegations contained in Paragraph 51 of the Complaint, and on that basis, denies them.
- 52. Mentor states that the December 2011 Joint Committee Opinion of the American College of Obstetricians and Gynecologists and the American Urogynecologic Society referenced in Paragraph 52 speaks for itself and Mentor refers to the complete Opinion for a full statement of its contents. Mentor denies, generally and specifically, the remaining allegations contained in Paragraph 52 of the Complaint.
- 53. Mentor states that the December 2011 Joint Committee Opinion of the American College of Obstetricians and Gynecologists and the American Urogynecologic Society referenced in Paragraph 53 speaks for itself and Mentor refers to the complete Opinion for a full statement of its contents. Mentor denies, generally and specifically, the remaining allegations contained in Paragraph 53 of the Complaint.

- 54. Mentor is without information or knowledge sufficient to form a belief as to the truth of the allegations contained in Paragraph 54 of the Complaint, and on that basis, denies them.
- 55. Mentor states that the quoted publication, "Surgical Mesh for Treatment of Women with Pelvic Organ Prolapse and Stress Urinary Incontinence" referenced in Paragraph 55 speaks for itself and Mentor refers to the complete publication for a full statement of its contents.
- 56. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 56 of the Complaint.
- 57. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 57 of the Complaint.
- 58. Mentor is without information or knowledge sufficient to form a belief as to the truth of the allegations contained in Paragraph 58 of the Complaint, and on that basis, denies them.
- 59. In response to Paragraph 59 of the complaint, Mentor denies that it currently makes the referenced statement as it does not currently distribute Aris. Mentor is without information or knowledge sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 59, and on that basis, denies them.
- 60. Mentor states that the medical and scientific literature referenced in Paragraph 60 speaks for itself and Mentor refers to the complete medical and scientific literature for a full statement of its contents. Mentor denies, generally and specifically, the remaining allegations contained in Paragraph 60 of the Complaint.

- 61. In response to Paragraph 61 of the complaint, Mentor denies that it makes the referenced statement as it does not distribute Novasilk. Mentor is without information or knowledge sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 61, and on that basis, denies them.
- 62. Mentor states that the scientific and medical literature referenced in Paragraph 62 speaks for itself and Mentor refers to the complete medical and scientific literature for a full statement of its contents. Mentor denies, generally and specifically, the remaining allegations contained in Paragraph 62 of the Complaint.
- 63. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 63 of the Complaint.
- 64. In response to Paragraph 64 of the Complaint, Mentor denies that it currently markets any transvaginal or pelvic mesh products. Mentor is without information or knowledge sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 64, and on that basis, denies them.
- 65. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 65 of the Complaint.
- 66. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 66 of the Complaint.
- 67. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 67 of the Complaint, including subparts (a)-(j).
- 68. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 68 of the Complaint, including subparts (a)-(t).

- 69. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 69 of the Complaint.
- 70. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 70 of the Complaint.
- 71. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 71 of the Complaint.
- 72. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 72 of the Complaint.
- 73. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 73 of the Complaint.
- 74. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 74 of the Complaint.
- 75. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 75 of the Complaint.
- 76. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 76 of the Complaint.
- 77. Mentor is without information or knowledge sufficient to form a belief as to the truth of the allegations contained in Paragraph 77 of the Complaint, and on that basis, denies them.
- 78. Mentor is without information or knowledge sufficient to form a belief as to the truth of the allegations contained in Paragraph 78 of the Complaint, and on that basis, denies them.

- 79. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 79 of the Complaint.
- 80. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 80 of the Complaint.
- 81. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 81 of the Complaint.
- 82. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 82 of the Complaint.
- 83. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 83 of the Complaint.
- 84. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 84 of the Complaint.
- 85. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 85 of the Complaint.
- 86. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 86 of the Complaint.
- 87. Mentor is without information or knowledge sufficient to form a belief as to the truth of the allegations contained in Paragraph 87 of the Complaint, and on that basis, denies them.
- 88. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 88 of the Complaint.

- 89. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 89 of the Complaint.
- 90. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 90 of the Complaint.
- 91. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 91 of the Complaint.
- 92. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 92 of the Complaint.
- 93. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 93 of the Complaint.
- 94. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 94 of the Complaint.

# V. RESPONSE TO CAUSES OF ACTION COUNT I: NEGLIGENCE

- 95. Mentor incorporates by reference the admissions, denials, and averments of Paragraphs 1–94 of this Answer as if fully rewritten herein.
- 96. The allegations contained in Paragraph 96 of the Complaint are legal conclusions that do not require an answer. To the extent that Mentor is required to answer, Mentor denies, generally and specifically, each and every allegation of Paragraph 96.
- 97. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 97 of the Complaint, including subparts (a)-(e).

- 98. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 98 of the Complaint, including subparts (a)-(i).
- 99. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 99 of the Complaint, including subparts (a)-(u).
- 100. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 100 of the Complaint, including subparts (a)-(c).
- 101. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 101 of the Complaint.
- 102. In response to Paragraph 102 of the Complaint, Mentor denies that it is liable to Plaintiffs for the requested relief or any relief whatsoever.

# **COUNT II: STRICT LIABILITY - DESIGN DEFECT**

- 103. Mentor incorporates by reference the admissions, denials, and averments of Paragraphs 1–102 of this Answer as if fully rewritten herein.
- 104. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 104 of the Complaint, including subparts (a)-(l).
- 105. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 105 of the Complaint.
- 106. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 106 of the Complaint.
- 107. In response to Paragraph 107 of the Complaint, Mentor denies that it is liable to Plaintiffs for the requested relief or any relief whatsoever.

# COUNT III: STRICT LIABILITY - MANUFACTURING DEFECT

- 108. Mentor incorporates by reference the admissions, denials, and averments of Paragraphs 1–107 of this Answer as if fully rewritten herein.
- 109. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 109 of the Complaint.
- 110. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 110 of the Complaint.
- 111. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 111 of the Complaint.
- 112. In response to Paragraph 112 of the Complaint, Mentor denies that it is liable to Plaintiffs for the requested relief or any relief whatsoever.

# **COUNT IV: STRICT LIABILITY - FAILURE TO WARN**

- 113. Mentor incorporates by reference the admissions, denials, and averments of Paragraphs 1–112 of this Answer as if fully rewritten herein.
- 114. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 114 of the Complaint.
- 115. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 115 of the Complaint.
- 116. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 116 of the Complaint.
- 117. In response to Paragraph 117 of the Complaint, Mentor denies that it is liable to Plaintiffs for the requested relief or any relief whatsoever.

# COUNT V: STRICT LIABILITY - DEFECTIVE PRODUCT

- 118. Mentor incorporates by reference the admissions, denials, and averments of Paragraphs 1–117 of this Answer as if fully rewritten herein.
- 119. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 119 of the Complaint.
- 120. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 120 of the Complaint.
- 121. In response to Paragraph 121 of the Complaint, Mentor admits that Plaintiffs from the referenced jurisdictions are asserting the referenced claims. Mentor denies that Plaintiffs are entitled to any relief from the asserted claims. Mentor denies, generally and specifically, each and every remaining allegation of Paragraph 121.
- 122. In response to Paragraph 122 of the Complaint, Mentor admits that Plaintiffs are asserting the referenced claims. Mentor denies that Plaintiffs are entitled to any relief from the asserted claims. Mentor denies, generally and specifically, each and every remaining allegation of Paragraph 122.
- 123. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 123 of the Complaint.
- 124. In response to Paragraph 124 of the Complaint, Mentor denies that it is liable to Plaintiffs for the requested relief or any relief whatsoever.

# **COUNT VI: BREACH OF EXPRESS WARRANTY**

125. Mentor incorporates by reference the admissions, denials, and averments of Paragraphs 1–124 of this Answer as if fully rewritten herein.

- 126. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 126 of the Complaint.
- 127. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 127 of the Complaint.
- 128. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 128 of the Complaint.
- 129. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 129 of the Complaint.
- 130. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 130 of the Complaint.
- 131. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 131 of the Complaint.
- 132. In response to Paragraph 132 of the Complaint, Mentor denies that it is liable to Plaintiffs for the requested relief or any relief whatsoever.

## **COUNT VII: BREACH OF IMPLIED WARRANTY**

- 133. Mentor incorporates by reference the admissions, denials, and averments of Paragraphs 1–132 of this Answer as if fully rewritten herein.
- 134. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 134 of the Complaint.
- 135. Mentor is without information or knowledge sufficient to form a belief as to the truth of the allegations contained in Paragraph 135 of the Complaint, and on that basis, denies them.

- 136. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 136 of the Complaint.
- 137. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 137 of the Complaint.
- 138. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 138 of the Complaint.
- 139. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 139 of the Complaint.
- 140. In response to Paragraph 140 of the Complaint, Mentor denies that it is liable to Plaintiffs for the requested relief or any relief whatsoever.

# **COUNT VIII: FRAUDULENT CONCEALMENT**

- 141. Mentor incorporates by reference the admissions, denials, and averments of Paragraphs 1–140 of this Answer as if fully rewritten herein.
- 142. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 142 of the Complaint.
- 143. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 143 of the Complaint.
- 144. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 144 of the Complaint.
- 145. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 145 of the Complaint.

- 146. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 146 of the Complaint, including subparts (a)-(c).
- 147. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 147 of the Complaint.
- 148. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 148 of the Complaint.
- 149. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 149 of the Complaint.
- 150. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 150 of the Complaint.
- 151. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 151 of the Complaint.
- 152. In response to Paragraph 152 of the Complaint, Mentor denies that it is liable to Plaintiffs for the requested relief or any relief whatsoever.

## **COUNT IX: CONSTRUCTIVE FRAUD**

- 153. Mentor incorporates by reference the admissions, denials, and averments of Paragraphs 1–152 of this Answer as if fully rewritten herein.
- 154. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 154 of the Complaint.
- 155. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 155 of the Complaint.

- 156. Mentor is without information or knowledge sufficient to form a belief as to the truth of the allegations contained in Paragraph 156 of the Complaint, and on that basis, denies them.
- 157. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 157 of the Complaint.
- 158. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 158 of the Complaint.
- 159. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 159 of the Complaint.
- 160. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 160 of the Complaint.
- 161. In response to Paragraph 161 of the Complaint, Mentor denies that it is liable to Plaintiffs for the requested relief or any relief whatsoever.

# COUNT X: DISCOVERY RULE, TOLLING, AND FRAUDULENT CONCEALMENT

- 162. Mentor incorporates by reference the admissions, denials, and averments of Paragraphs 1–161 of this Answer as if fully rewritten herein.
- 163. In response to Paragraph 163 of the Complaint, Mentor admits that Plaintiffs are asserting the referenced tolling and extension theories. Mentor denies that Plaintiffs are entitled to the application of any such theories, or the relief requested. Mentor denies, generally and specifically, each and every remaining allegation of Paragraph 163.
- 164. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 164 of the Complaint.

- 165. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 165 of the Complaint.
- 166. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 166 of the Complaint.

# **COUNT XI: NEGLIGENT MISREPRESENTATION**

- 167. Mentor incorporates by reference the admissions, denials, and averments of Paragraphs 1–166 of this Answer as if fully rewritten herein.
- 168. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 168 of the Complaint.
- 169. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 169 of the Complaint.
- 170. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 170 of the Complaint.
- 171. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 171 of the Complaint.
- 172. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 172 of the Complaint.
- 173. In response to Paragraph 173 of the Complaint, Mentor denies that it is liable to Plaintiffs for the requested relief or any relief whatsoever.

# **COUNT XII: NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS**

174. Mentor incorporates by reference the admissions, denials, and averments of Paragraphs 1–173 of this Answer as if fully rewritten herein.

- 175. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 175 of the Complaint.
- 176. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 176 of the Complaint.
- 177. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 177 of the Complaint.
- 178. In response to Paragraph 178 of the Complaint, Mentor denies that it is liable to Plaintiffs for the requested relief or any relief whatsoever.

# COUNT XIII: VIOLATION OF CONSUMER PROTECTION LAWS

- 179. Mentor incorporates by reference the admissions, denials, and averments of Paragraphs 1–178 of this Answer as if fully rewritten herein.
- 180. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 180 of the Complaint.
- 181. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 181 of the Complaint.
- 182. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 182 of the Complaint.
- 183. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 183 of the Complaint.
- 184. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 184 of the Complaint.

- 185. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 185 of the Complaint.
- 186. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 186 of the Complaint.
- 187. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 187 of the Complaint.
- 188. The allegations contained in Paragraph 188 of the Complaint are legal conclusions that do not require an answer.
- 189. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 189 of the Complaint.
- 190. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 190 of the Complaint.
- 191. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 191 of the Complaint.
- 192. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 192 of the Complaint.
- 193. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 193 of the Complaint.
- 194. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 194 of the Complaint.

- 195. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 195 of the Complaint.
- 196. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 196 of the Complaint.
- 197. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 197 of the Complaint.
- 198. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 198 of the Complaint.
- 199. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 199 of the Complaint.
- 200. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 200 of the Complaint.
- 201. In response to Paragraph 201 of the Complaint, Mentor denies that it is liable to Plaintiffs for the requested relief or any relief whatsoever.

## **COUNT XIV: GROSS NEGLIGENCE**

- 202. Mentor incorporates by reference the admissions, denials, and averments of Paragraphs 1–201 of this Answer as if fully rewritten herein.
- 203. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 203 of the Complaint.
- 204. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 204 of the Complaint.

- 205. Mentor is without information or knowledge sufficient to form a belief as to the truth of the allegations contained in Paragraph 205 of the Complaint, and on that basis, denies them.
- 206. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 206 of the Complaint.
- 207. In response to Paragraph 207 of the Complaint, Mentor denies that it is liable to Plaintiffs for the requested relief or any relief whatsoever.

## **COUNT XV: UNJUST ENRICHMENT**

- 208. Mentor incorporates by reference the admissions, denials, and averments of Paragraphs 1–207 of this Answer as if fully rewritten herein.
- 209. Mentor is without information or knowledge sufficient to form a belief as to the truth of the allegations contained in Paragraph 209 of the Complaint, and on that basis, denies them.
- 210. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 210 of the Complaint.
- 211. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 211 of the Complaint.
- 212. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 212 of the Complaint.
- 213. In response to Paragraph 213 of the Complaint, Mentor denies that it is liable to Plaintiffs for the requested relief or any relief whatsoever.

# **COUNT XVI: LOSS OF CONSORTIUM**

- 214. Mentor incorporates by reference the admissions, denials, and averments of Paragraphs 1–213 of this Answer as if fully rewritten herein.
- 215. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 215 of the Complaint.
- 216. In response to Paragraph 216 of the Complaint, Mentor denies that it is liable to Plaintiffs for the requested relief or any relief whatsoever.

# **COUNT XVII: PUNITIVE DAMAGES**

- 217. Mentor incorporates by reference the admissions, denials, and averments of Paragraphs 1–216 of this Answer as if fully rewritten herein.
- 218. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 218 of the Complaint.
- 219. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 219 of the Complaint.
- 220. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 220 of the Complaint.
- 221. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 221 of the Complaint.
- 222. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 222 of the Complaint.
- 223. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 223 of the Complaint.

- 224. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 224 of the Complaint.
- 225. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 225 of the Complaint.
- 226. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 226 of the Complaint.
- 227. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 227 of the Complaint.
- 228. Mentor denies, generally and specifically, each and every allegation contained in Paragraph 228 of the Complaint.

# **RESPONSE TO PRAYER FOR RELIEF**

- 229. In response to Plaintiffs' "Prayer for Relief" section and the "Wherefore" clauses contained therein, including subparts (1)–(10), Mentor denies that it is liable to Plaintiffs for the requested relief or any relief whatsoever.
- 230. Mentor denies any allegation contained in the Complaint that is not herein expressly admitted by Mentor.

## AFFIRMATIVE DEFENSES

Mentor maintains that discovery and investigation may reveal that one or more of the following affirmative defenses should be available to Mentor in this matter. Mentor, therefore, asserts said defenses to preserve the right to assert them as separate and distinct affirmative defenses to the Complaint and to the causes of action therein. Upon completion of discovery, and if the facts warrant, Mentor may withdraw any of its defenses as may be appropriate.

Further, Mentor reserves the right to amend this Answer to assert additional claims or defenses as discovery proceeds.

## FIRST AFFIRMATIVE DEFENSE

(<u>Failure to State a Claim</u>)

The Complaint fails to state a claim upon which relief can be granted.

## SECOND AFFIRMATIVE DEFENSE

(Statute of Limitations, Statute of Repose and Laches)

The claims against Mentor are barred, in whole or in part, by laches and/or the applicable statute of limitations or statutes of repose.

#### THIRD AFFIRMATIVE DEFENSE

(Insufficient Service of Process)

The Complaint must be dismissed due to insufficient service of process.

#### FOURTH AFFIRMATIVE DEFENSE

(Joinder)

The Complaint fails to join indispensable parties necessary for the just adjudication of this matter.

## FIFTH AFFIRMATIVE DEFENSE

(Waiver and Estoppel)

The claims against Mentor are barred, in whole or in part, by waiver and/or estoppel.

## SIXTH AFFIRMATIVE DEFENSE

(Comparative/Contributory Negligence)

If Plaintiffs sustained damages by reason of the matters alleged in the Complaint, which is denied, then said damages were caused in whole or in part by Plaintiffs' own negligence and fault and were not caused or contributed to in any manner, by any alleged fault, negligence or

breach of warranty of Mentor, its officers, agents, contractors, servants, employees, or others for whom it was responsible. Plaintiffs' recovery should be diminished by that percentage of fault attributable to Plaintiffs and/or persons or entities other than Mentor for those injuries sustained by Plaintiffs upon which the damages complained of in this action are based. Thus, Mentor's liability, if any, is limited to its percentage of responsibility for the injuries of Plaintiffs, if any, regardless of whether or not other persons or entities are named as co-defendants.

#### SEVENTH AFFIRMATIVE DEFENSE

## (Fault of Others)

If Plaintiffs sustained damages as alleged in the Complaint, which is denied, said damages were caused solely by or contributed to by the acts and fault of third parties and were not caused or contributed to by any acts or fault of Mentor, its officers, agents, servants, employees, contractors, or others for whom it was responsible. Mentor will identify the other persons or entities that may have been responsible with as much particularity as is feasible as discovery progresses and in sufficient time to allow the Plaintiffs to respond and/or file pleadings. Thus, Plaintiffs' claims should be barred or proportionately reduced by the intentional and/or negligent acts of such known or unknown third parties.

#### EIGHTH AFFIRMATIVE DEFENSE

## (Mitigation of Damages)

If Plaintiffs sustained damages as alleged in the Complaint, which is denied, Plaintiffs have failed to mitigate their damages and any recovery is to be diminished by the degree to said failure to mitigate.

#### NINTH AFFIRMATIVE DEFENSE

## (Assumption of Risk)

The allegations set forth in the Complaint are barred on the grounds that Plaintiffs knew, or in the exercise of ordinary care should have known, of the risk of the injuries or damages alleged in the Complaint, if any, and nevertheless did expressly, freely, and voluntarily assume said risk, and this undertaking proximately caused and contributed to the losses, injuries or damages, if any, alleged by Plaintiffs.

#### TENTH AFFIRMATIVE DEFENSE

# (Assumption of Risk/Informed Consent)

Upon information and belief, Plaintiffs had full knowledge of the risks and possible adverse effects pertaining to the procedures performed upon them, and all or part of the alleged injuries, damages, and/or losses, if any, sustained by Plaintiffs arose from and were caused by risks of which Plaintiffs were aware, and such risks were accepted and assumed by Plaintiffs, and for that reason any recovery against Mentor should be diminished, reduced, offset, or barred in accordance with the principles of assumption of the risk and/or informed consent.

## **ELEVENTH AFFIRMATIVE DEFENSE**

## (Collateral Sources)

Mentor is entitled to a set-off from any recovery against it to the extent each item of economic loss alleged in the Complaint was, or with reasonable certainty will be, replaced or indemnified, in whole or in part, by collateral sources.

#### TWELFTH AFFIRMATIVE DEFENSE

## (Superior Knowledge of Plaintiffs' Physicians and Medical Care Providers)

At all times relevant hereto, the knowledge of Plaintiffs' physicians and/or other medical care providers with respect to the possible risks of surgery and the opportunity to warn of the

possible risks of surgery, was superior to that of Mentor, and, therefore, if there was any duty to warn Plaintiffs of the risks of surgery, it was the duty of said physicians and/or other medical care providers, not of Mentor, and breach of that duty was an intervening and/or superseding cause of the injuries alleged by Plaintiffs.

#### THIRTEENTH AFFIRMATIVE DEFENSE

(Plaintiffs' Physicians/Medical Care Providers Were Sophisticated Users)

Plaintiffs' physicians and/or medical care providers, including their agents, servants and employees, by reason of the warnings and handling information given to them and their own long standing and continuous experience with the products or materials, if any, referred to in the Complaint, are and were sophisticated users of any and all such products or materials, and thereby acquired a separate and affirmative duty to warn Plaintiffs of any alleged potential harmful effects from the use or misuse of said products or materials. By reason of the foregoing, the failure of said physicians and/or medical care providers to discharge said duty directly and proximately caused any and all damages and injuries, if any, complained of by Plaintiffs.

#### FOURTEENTH AFFIRMATIVE DEFENSE

# (Learned Intermediary)

The devices referred to in the Complaint are medical devices available only upon the prescription and/or order of a licensed physician and/or surgeon and are not available to the general public. Mentor provided information concerning warnings, precautions, and complications to those persons to whom the medical devices were available. Thus, Plaintiffs' claims are barred, in whole or in part, by the "learned intermediary" doctrine.

#### FIFTEENTH AFFIRMATIVE DEFENSE

## (Adequate Warnings)

If it is proven at the time of trial that Plaintiffs came into contact with Mentor's product, which is denied, then any product manufactured and/or sold and/or distributed by Mentor which was or may have been furnished to Plaintiffs and which they came into contact or may have come into contact with, was furnished with adequate and appropriate warnings.

## SIXTEENTH AFFIRMATIVE DEFENSE

## (Alteration of Products)

Plaintiffs' physicians and/or medical care providers may have modified, altered or changed the Mentor products, if any, referred to in the Complaint, so that such changes in any said products or materials proximately caused Plaintiffs' injuries, loss and damages, if any.

#### SEVENTEENTH AFFIRMATIVE DEFENSE

#### (Benefits Outweigh Risks)

The benefits of Mentor products or materials, if any, referred to in the Complaint outweigh the risk of danger and/or harm, if any, inherent in said products or materials.

#### EIGHTEENTH AFFIRMATIVE DEFENSE

## (No Representation to the Public)

With respect to the medical devices referred to in the Complaint, if any were manufactured by Mentor, no representations were made by Mentor to the public at large in order to induce purchase of said products or materials.

#### NINETEENTH AFFIRMATIVE DEFENSE

## (Independent, Intervening, or Superseding Cause)

Plaintiffs' injuries, if any, were proximately caused by unforeseeable, independent, intervening and/or superseding event(s) beyond the control, and unrelated to any conduct, of

Mentor. Mentor's actions or omissions, if any, were superseded by the negligence and wrongful conduct of others.

#### TWENTIETH AFFIRMATIVE DEFENSE

#### (Alternate Cause)

The injuries and damages of which Plaintiffs complain were not caused by any product distributed by Mentor, but were caused by some other product, process, occurrence, event or service over which Mentor exercised no control or right of control.

#### TWENTY-FIRST AFFIRMATIVE DEFENSE

# (Preemption of Federal Law)

Federal statutes and regulations preempt all state law governing the products that are the subject of the Complaint, and said products were in compliance with federal law at all times relevant to this cause of action.

#### TWENTY-SECOND AFFIRMATIVE DEFENSE

## (Restatement (Second) of Torts)

The claims against Mentor are barred, in whole or in part, by the provisions of Comments "j" and "k" to Section 402 of the Restatement (Second) of Torts.

## TWENTY-THIRD AFFIRMATIVE DEFENSE

#### (State of the Art)

Any and all acts performed by, and products designed and manufactured and/or distributed by Mentor were at all times relevant to the Complaint in conformity with the state of the art for the design and manufacture of such similar devices, and thus Plaintiffs' claims are barred.

#### TWENTY-FOURTH AFFIRMATIVE DEFENSE

(State of the Art)

The actions of Mentor were in compliance with all existing safety standards and precautions then consistent with the state of the medical art, and thus, Plaintiffs' claims are barred.

#### TWENTY-FIFTH AFFIRMATIVE DEFENSE

(Open and Obvious)

Any dangers associated with the use of the medical devices that may have caused Plaintiffs' injuries, if any, were open and obvious, and Plaintiffs are therefore barred from recovery.

## TWENTY-SIXTH AFFIRMATIVE DEFENSE

(<u>Idiosyncratic Reaction</u>)

Some or all of the injuries alleged in the Complaint were caused or aggravated by Plaintiffs' pre-existing medical conditions or exposure to other substances utilized throughout their lifetimes, by Plaintiffs' unusual susceptibility to injury, or by their idiosyncratic reactions.

#### TWENTY-SEVENTH AFFIRMATIVE DEFENSE

(Conformity with Governmental Regulations)

Any and all warnings or information pertaining to products designed, manufactured and/or distributed and/or sold by Mentor were at all times relevant to the Complaint in conformity with governmental requirements.

#### TWENTY-EIGHTH AFFIRMATIVE DEFENSE

(Conformity with Governmental Standards)

The formula, labeling, and/or design of any products designed, manufactured and/or distributed and/or sold by Mentor at all times relevant to the Complaint complied with

mandatory safety standards or regulations adopted and promulgated by the federal government or an agency of the federal government, entitling Mentor to a rebuttable presumption that Mentor is not liable for any harm to Plaintiffs as claimed in the Complaint.

#### TWENTY-NINTH AFFIRMATIVE DEFENSE

## (UCC Defenses)

Mentor is entitled to the benefits of all defenses and presumptions contained in, or arising from, any Uniform Commercial Code provisions enacted by the states of Plaintiffs' residencies, or by any other states whose laws are deemed to apply in this case.

#### THIRTIETH AFFIRMATIVE DEFENSE

(Unintended and Unforeseeable Misuse, Modification, or Abuse of the Product)

If any product manufactured, distributed or sold by Mentor caused harm as alleged, which is denied, then such harm was proximately caused by misuse, modification, and/or abuse of the product in a manner neither intended nor foreseen by Mentor.

#### THIRTY-FIRST AFFIRMATIVE DEFENSE

(No Feasible Alternative Design)

Mentor states that there is no alternative design for the product that was capable of preventing Plaintiffs' injuries.

## THIRTY-SECOND AFFIRMATIVE DEFENSE

#### (Preemption)

The conduct of Mentor and all activities with respect to the subject product have been and are under the supervision of the United States Food and Drug Administration. Accordingly, this action is barred by the doctrine of primary jurisdiction and preemption.

## THIRTY-THIRD AFFIRMATIVE DEFENSE

(Accord and Satisfaction/Release)

Plaintiffs' claims are barred by the doctrine of accord and satisfaction and/or release.

## THIRTY-FOURTH AFFIRMATIVE DEFENSE

(Restatement (Third) of Torts)

The claims against Mentor are barred, in whole or in part, by the provisions of Section 6(c) and/or Section 19 of the Restatement (Third) of Torts.

#### THIRTY-FIFTH AFFIRMATIVE DEFENSE

(Improper Pleading)

To the extent that Plaintiffs' Complaint purports to state claims for fraud and/or misrepresentation, the Complaint fails to comply with the requirements of Rule 9(b) of the Federal Rules of Civil Procedure and should be dismissed.

#### THIRTY-SIXTH AFFIRMATIVE DEFENSE

(Damages Unrecoverable)

All or some of Plaintiffs' claims for damages have not accrued and are too speculative, uncertain, and contingent to be recoverable.

## THIRTY-SEVENTH AFFIRMATIVE DEFENSE

(<u>Punitive Damages Unconstitutional</u>)

Plaintiffs' claims for punitive damages are in contravention of Mentor's rights under each of the following constitutional provisions:

- a. the Commerce Clause of Article I, Section 8 of the United States Constitution;
- b. the Contracts Clause of Article I, Section 10 of the United States Constitution;
- c. the prohibition against ex post facto laws embodied in Article I, Section 10 of the United States Constitution:

- d. the Supremacy Clause of Article VI of the United States Constitution;
- e. the Free Speech Clause of the First Amendment of the United States Constitution;
- f. the Due Process Clause of the Fifth and Fourteenth Amendments of the United States Constitution;
- g. the Takings Clause of the Fifth Amendment of the United States Constitution
- h. the Right to Counsel of the Sixth Amendment of the United States Constitution;
- the Excessive Fines Clause of the Eighth Amendment of the United States
   Constitution;
- j. the Right to Trial by Jury contained in the Seventh Amendment of the United States Constitution;
- k. the Equal Protection Clause of the Fourteenth Amendment of the United States
   Constitution; and
- 1. similar or corresponding provisions of the constitutions of the states of Plaintiffs' residencies, or of any other states whose laws are deemed to apply in this case.

#### THIRTY-EIGHTH AFFIRMATIVE DEFENSE

## (Punitive Damages Barred)

No act or omission of Mentor was due to an evil motive or a reckless indifference to the rights of others; therefore, any award of punitive damages is barred.

#### THIRTY-NINTH AFFIRMATIVE DEFENSE

#### (Punitive Damages Barred)

With respect to Plaintiffs' demand for punitive damages, Mentor specifically incorporates by reference any and all standards, caps or limitations regarding the determination and enforceability of punitive damage under applicable state law or other applicable law.

#### FORTIETH AFFIRMATIVE DEFENSE

## (Punitive Damages Barred)

With respect to Plaintiffs' demand for punitive damages, Mentor specifically incorporates by reference any and all standards, caps or limitations regarding the determination and enforceability of punitive damage awards that are set forth in *Philip Morris USA v. Williams*, 127 S. Ct. 1057 (2007), *State Farm Mutual Automobile Insurance Co. v. Campbell*, 538 U.S. 408 (2003), *BMW of North America, Inc. v. Gore*, 517 U.S. 559 (1996), and similar State cases and statutes.

## FORTY-FIRST AFFIRMATIVE DEFENSE

# (<u>Punitive Damages Barred</u>)

Because of the lack of clear standards, any imposition of punitive damages against Mentor would be unconstitutionally vague and/or overbroad.

#### FORTY-SECOND AFFIRMATIVE DEFENSE

#### (No Warranty)

Plaintiffs and/or their physicians and/or medical care providers did not receive, directly or indirectly, nor rely upon any express or implied warranty from Mentor, or, if so, any breach thereof by Mentor was not a proximate cause of Plaintiffs' injuries or damages as alleged in the Complaint.

#### FORTY-THIRD AFFIRMATIVE DEFENSE

#### (Disclaimer)

Any express of implied warranties alleged to have been made by Mentor were disclaimed.

#### FORTY-FOURTH AFFIRMATIVE DEFENSE

(Lack of Notice/Privity)

The claims for breach of warranty are barred by the lack of privity between Plaintiffs and Mentor and/or by Plaintiffs' failure to provide Mentor requisite or timely notice of any claimed breach of warranty.

## FORTY-FIFTH AFFIRMATIVE DEFENSE

(Prescription and Peremption)

Plaintiffs' claims are barred in whole or in part by prescription and/or peremption.

#### FORTY-SIXTH AFFIRMATIVE DEFENSE

(Products Liability Acts)

Plaintiffs' claims are governed by and barred in whole or in part by the Product Liability Acts of the states of Plaintiffs' residencies, or by the Product Liability Acts of any other states whose laws are deemed to apply in this case.

#### FORTY-SEVENTH AFFIRMATIVE DEFENSE

(Medical Monitoring)

Plaintiffs' claims for medical monitoring are barred by the rules, statutes, or common law of any states whose laws are deemed to apply in this case.

#### FORTY-EIGHTH AFFIRMATIVE DEFENSE

(State-Specific Defenses)

Mentor pleads all additional defenses available to it under the rules, statutes, or common law of any states whose laws are deemed to apply in this case.

# FORTY-NINTH AFFIRMATIVE DEFENSE

(Notice of Additional Affirmative Defenses)

Mentor hereby gives notice that it intends to rely upon such other affirmative defenses as may become available or apparent during the course of discovery and thus reserves the right to amend its Answer to assert such defenses. Mentor further gives notice that it intends to rely upon and incorporates by reference any affirmative defenses that may be asserted by any codefendant in this lawsuit.

## **DEMAND FOR JURY TRIAL**

Defendant Mentor Worldwide LLC demands a jury trial of all issues so triable.

WHEREFORE, Defendant Mentor Worldwide LLC prays as follows:

- That Plaintiffs take nothing by virtue of the Complaint herein and that this action be dismissed in its entirety;
- 2. For costs of suit and attorneys' fees herein incurred; and
- 3. For such other and further relief as the Court may deem just and proper.

Respectfully submitted,

s/ Dustin B. Rawlin

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Attorneys for Defendant Mentor Worldwide LLC

# **CERTIFICATE OF SERVICE**

I hereby certify that on January 28, 2013, a copy of the foregoing *Defendant Mentor* Worldwide LLC's Answer and Affirmative Defenses to Plaintiffs' First Amended Master Long Form Complaint and Jury Demand was filed via ECF and by electronic mail on the following counsel:

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s/ Dustin B. Rawlin
Dustin B. Rawlin
Attorney for Defendant Mentor Worldwide LLC